CONSULTANT'S CORNER

IATROGENIC DRUG RELATED DISEASES

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IN THIS ISSUE, WE CONTINUE A COLUMN FEATURING COMMENTS FROM A SENIOR CONSULTANT TO FELLOW CLINICIANS ON A MEDICOLEGAL TOPIC.

Iatrogenic drug related diseases, also referred to as drug induced diseases (DID), generate a significant number of malpractice suits. In my personal experience, with a selection bias favoring "medicine" oriented liability claims over "surgery" claims, they can account for almost 25 percent of claims.

DID alters normal anatomy and physiology. These alterations may be minimal, severe, temporary, permanent or lethal. Risk free medications do not exist. In the absence of a history of allergy, the clinician may have no basis to predict that a particular patient will suffer a specific injury from a certain drug. It is noteworthy that the incidence of severely debilitating DID is relatively infrequent, while transitory reactions are somewhat common. How does a physician avoid liability in such cases?

When another submission to *Legal Medicine Open File* about drug induced diseases was requested, I recalled that my prior articles dealt with DID in a more formalized and standard medicolegal manner, one that included a somewhat didactic application of legal principles, such as negligence or informed consent. While that approach is acceptable, I am convinced that, ultimately, medical professional liabilities are best managed through the pursuit and the exercise of clinical competence rather than with any attempt at defensive medicine premised alone on anxiety. I have consulted with physicians for many years about medicolegal issues, and it is my sad conclusion that we have allowed ourselves to become intimidated by the law. It is frustrating to me that so many members of the noblest profession have become conditioned to fear the law and to attempt to walk the apparent path of least resistance, the practice of defensive medicine. Ultimately, the latter easily leads to the loss of a precious resource, the clinician's time, and may paradoxically cause its own adverse outcomes, especially when costly and highly invasive diagnostic studies are pursued. Being realistic, I fully appreciate the justifiable concern on the part of clinicians regarding the possible, adverse legal consequences of medical practice. Occasional, erratic court determinations that seemingly defy reason cannot be ignored. Nevertheless, physicians are best advised to exercise their own clinical skills, those accumulated through education, training and experience. They are the clearest guide to legally accepted practice. In other words, no special training is required to avoid DID liability. Good medicine is good law.

It is an ethical obligation of physicians to diagnose and treat patients in accordance with acceptable standards of practice. Ethical duties are imposed upon professionals by their own community of peers. On the other hand,

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a legal duty is imposed by law. The latter is an expression of a societal expectation that a person should behave in a specific manner under certain circumstances. For example, the common law imposed no duty to rescue another in distress. Ethical duties, however, could impose such an obligation in certain circumstances. Lastly, a moral duty, i.e., one that is self imposed only, might obligate one to act in such a case, absent either a legal or an ethical duty. In any event, physicians who closely adhere to all ethical duties imposed by the medical profession will almost assuredly overcome any allegations of malpractice. This is especially true when pertinent medical records reflect, directly or indirectly, that standard procedures were followed. Once again, good medicine is good law; the former encompasses the latter.

In the prescription of medications, what kind of clinical conduct is expected of a practicing physician by the medical profession? As a general rule, the physician is expected to prescribe medications that are reasonably indicated for the diagnosed condition and to communicate with the patient the nature of the disease, the expected results of treatment, the risks of treatment, and the need for appropriate follow-up. If the patient refuses treatment in such a setting, the clinician should carefully inform the patient about the consequences of that refusal and notate the pertinent medical record accordingly. What does the legal profession expect? Generally, the law expects that medications are dispensed when reasonably indicated, that the patient is allowed to make an informed decision about treatment or the refusal to undergo treatment, and that the patient is carefully instructed about the need for follow-up monitoring. Again, there is a general concordance of the expectations on the part of a clinician by both the legal and the medical professions.

On occasion, I have been struck that there are many doctors who appear to be absolutists about pharmaco-therapeutics. Apparently, they have convinced themselves that their approach to the dispensing of medications is the best and the only appropriate form of treatment. In their minds, there is a minimalization of the notion that competent physicians can hold respectable differences of opinion about the appropriate treatment for a specific case. It seems, further, that absolutists are attractive to lawyers and to jurors, perhaps due to the clarity and forcefulness of their positions. It is axiomatic for clinicians that the first commandment regarding the prescription of medications is to be certain that the clinical indications support the selected drug. If a second or a third line medication is dispensed instead, a comment should be added in the medical record supporting that choice, e.g., that there was a history of allergy, a potential for serious drug interaction, or other controlling clinical circumstances. In a recent dispute in which I participated that involved the potential for disciplining a practitioner, the clinician in jeopardy of experiencing a license sanction had prescribed a single dose of ampicillin, an available medication, very late in the evening for the treatment of a nursing home patient with cellulitis. The small facility itself contained no pharmacy. The reviewers were aware that the textbook drug of choice favored cephalexin or some similar agent, because its spectrum included coverage for the 7-10 percent chance that a cellulitis might be due to a *Staph* organism. Ampicillin, however, the only medication actually available at that late hour, should be effective in more than 90 percent of cases of similar cellulitis, because most are due to sensitive *Strep* or similar organisms. The patient's condition remained stabilized through the evening in question, and her medication was changed to cephalexin the next morning. Two peer reviewers of the case adamantly insisted, regardless of the complete circumstances prevailing, that the clinician had breached the applicable standard of care. Initially, a sanctioning of the physician was suggested; however, that action was reversed on appeal to a complete board of physician reviewers.

It is not possible to overemphasize the need for physicians to communicate with patients about the serious side effects of treatment with medications. In our society, the legal recognition of individual autonomy, i.e., the right of self-determination, should be kept in mind by all practicing physicians. Clearly, a mentally competent patient is endowed with a recognized right to refuse any treatment when the patient understands the consequences of

that refusal and there are no substantial state interests that would support an overriding obligation to preserve human life. Today, such state interests have been seriously eroded by court determinations.

When medications are to be employed on a long term basis, the duty to communicate with patients is similarly critical. The code of ethics of the AMA directs physicians to inform their patients about the significant adverse consequences of all treatments. In the clinical setting of long term therapy with medications such as corticosteroids, antibiotics, antihypertensives, hypoglycemics, and other drugs with serious side effects, providers face both an ethical and a legal obligation to inform patients about serious inherent risks. Side effects such as aseptic necrosis, osteoporosis, gastrointestinal ulcerations, renal toxicity, and serious superinfections may need to be both communicated and documented by the clinician. There are practitioners who claim that, because they always inform their patients about the serious side effects of medications such as steroids, they do not bother to record those conversations. That may be so, but it is fairly well established that many patients do not remember informative sessions that actually occur. In studies involving surgical procedures, there are patients with no recollection of formal counseling sessions just days after treatment is rendered, and more than 50 percent of patients have little or no recollection of those sessions within weeks. The wisdom of some form of abbreviated but clinically pertinent documentation should be self evident.

Not every instance of drug induced disease is the result of medical negligence. DID can occur regardless of the proper clinical indications for dispensing a medicine and even in the face of appropriate communications with the patient. From my perspective, liability should never be imposed in the setting of the administration of medications when the clinician establishes and documents the reasonable indications for employing the medication (i.e., the rationale for its prescription), secures the consent of the patient, and appropriately monitors for both therapeutic effectiveness and the occurrence of adverse reactions.

Some clinicians argue that the need to document the rationale for prescribing a certain medication can be overemphasized, because there are circumstances when the prescribed treatment is fairly widely recognized, given the pertinent diagnosis. As a rule, penicillin is the drug of choice for *Strep* pharyngitis, and I concede there is little clinical reasoning to support excessively documenting the choice of such a medication. But there are other clinical circumstances where the chance of serious patient injury approaches the potential for expected benefits. The wise provider recognizes those circumstances and acts accordingly. The continued use of steroids in the presence of aseptic necrosis may be clinically justifiable. However, there is wisdom in notating the medical record with those justifications. Again, the need for careful communications with patients may be critical. Today, we are often involved in the long term treatment of asymptomatic patients for illnesses such as hypertension and hypercholesterolemia where the adverse consequences of treatment may be more readily realized than the chronic risks of the diseases.

CONCLUSION

It is my contention that effective risk management tools for physicians regarding drug treatments lie squarely in their own hands. The best guide for professional conduct always is sound medical science and practice. We should never permit ourselves to be unduly swayed by the latest, seemingly contradictory court determination. Those of us who act as peer reviewers should be mindful of the complete clinical circumstances involved in the care rendered and that reasonable practitioners can differ in choosing therapy. The three most important rules are easy to recite: communicate, communicate, communicate! Tell your patients, plainly, about their medical condition and the medication you have decided to employ, what they should expect from their treatment, what are the significant risks of that treatment, and what they must do to help you in follow-up. If you will forgive a parting comment, good medicine is good law.